



### Finding solutions, along with patients

Faced with ongoing deregulation, with companies overstepping their roles, and with decision makers and health authorities who still fail to make patients' interests their top priority, it is up to healthcare professionals to assure quality of care and maintain patient trust.

**Training and education.** Quality healthcare requires continuing education for healthcare professionals and reliable information for patients. This implies:

- basic education for all healthcare professionals in the principles of critical appraisal (*Rev Prescrire* n°320), so that they are in a position to analyse clinical assessment data on individual drugs, instead of relying solely on others' judgement (*Rev Prescrire* n°321); it is particularly important to be able to distinguish surrogate endpoints from robust outcomes that take adverse effects into account (*Rev Prescrire* n°320);
- searching SPCs for important "buried" information such as clinical trial data and adverse effects (*Rev Prescrire* n°319);
- being able to recognise a drug's pharmacological class, notably by using international nonproprietary names (INNs), in order to avoid exposing patients to known adverse effects (*Prescrire Int* n°108);

- reminding patients not to believe everything they read or hear in the media. Reports of research results in the lay media can be misleading: many researchers have a tendency to exaggerate the significance of their findings, both for financial reasons and for personal status (*Rev Prescrire* n°320);

- acknowledging one's errors, as part of a constructive attitude towards improving professional practice (*Prescrire Int* n°109).

**Mobilise!** The positive impact that healthcare professionals and patients can have on healthcare quality was illustrated by several events in 2010:

- a French physician succeeded in bringing the severe adverse effects of *benfluorex* (ex-Mediator<sup>®</sup>) to the public's attention (*Rev Prescrire* n°325 and [www.english.prescrire.org](http://www.english.prescrire.org)), and a national health insurer (Cnamts) commissioned a study of its adverse effects (issue 316 p. 114), both of which led to *benfluorex* being withdrawn from the French market;
- patient groups successfully lobbied for market reinstatement of 100-mg capsules of *efavirenz* that are adapted to the treatment of certain HIV-infected young children (*Rev Prescrire* n°320).

**Resist "medicalisation of life".** Disease-mongering continued unabated in 2010, especially in the field of mental health (*Rev Prescrire* n°321 and [www.english.prescrire.org](http://www.english.prescrire.org)). Thus, in draft version V of the Diagnostic and Statistical Manual (DSM), to be published in 2012, certain diagnostic criteria are bizarre and diagnostic thresholds for some illnesses have been lowered (*Rev Prescrire* n°323). In 2010, the indications for *sertraline* were extended to cover various anxiety disorders (panic disorder, social anxiety disorder, post-traumatic stress disorder) (*Rev Prescrire* n°316).

Companies are trying to get their products authorised for use in earlier stages of the disease concerned. For example, *glatiramer* is now authorised for suspected recent-onset multiple sclerosis (*Prescrire Int* n°108). This medicalisation serves companies' interests by expanding the market for their drugs, at the expense of patient safety and well-being.

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► Some of the advertisements banned by the French regulator (Afssaps) in 2010 are particularly informative:

- misleading comparison and overstated results for Alimta<sup>®</sup> (*pemetrexed*) and Loramyc<sup>®</sup> (*miconazole*) (*Rev Prescrire* n°318);
- minimisation of the risks of Botox<sup>®</sup> (*botulinum toxin A*) (*Rev Prescrire* n°318);
- overstated claims concerning the indications for Calciprat vitamine D3<sup>®</sup> (*calcium + vitamin D3*), Gardasil<sup>®</sup> (*papillomavirus vaccine 6, 11, 16, 18*), Lacteol<sup>®</sup> (*Lactobacillus acidophilus*) and Solacy<sup>®</sup> (*vitamin A + L cystine + sulphur + yeast*) (*Rev Prescrire* n°318; 323; 326);
- misleading information on the indications for Inofer<sup>®</sup> (*ferrous succinate*) (*Rev Prescrire* n°318);

- unfounded criticism of generic versions of Omexel<sup>®</sup> (*tamsulosin*) (*Rev Prescrire* n°318);

- overly positive presentation of Exforge<sup>®</sup> (*amlodipine + valsartan*) and Tareg<sup>®</sup> (*valsartan*) by opinion leaders (*Rev Prescrire* n°323).

In the United States, legal action taken against the company marketing *quetiapine* (Seroquel<sup>®</sup>) revealed the extent to which some firms are willing to go to promote their products: off-label promotion, financial incentives for physicians to write or even simply sign articles on off-label uses. The company was forced to refund public health insurers for the costs of unwarranted prescriptions (*Prescrire Int* n°112).

### Patients first!

In 2010, as in previous years, there was a dearth of real therapeutic advance as well as continued failings of policy makers and healthcare authorities, such as approval of poorly evaluated drugs with negative risk-benefit balances, or failure to withdraw them from the market.

Unable to rely on regulatory agencies and healthcare authorities, it is up to healthcare professionals to select drugs that truly benefit their patients and avoid needlessly exposing them to the risk of adverse effects.

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